Degussa

Degussa Corporation

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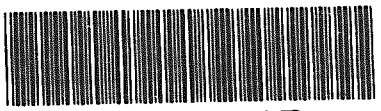

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Contains No CBI

Via Certified Mail R.R.R.
Z 761 467 485

November 22, 1996

Document Processing Center (TS-790)
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

Re: TSCA 8(e) Submission
Chemical name: 3-chloro-2-hydroxypropyltrimethylammonium chloride
CAS No. 3327-22-8

Dear Sir/Madam:

This information is being submitted by Degussa Corporation in accordance with TSCA Section 8(e). On November 11, 1996, we received notice of results of a skin painting study with 3-chloro-2-hydroxypropyltrimethylammonium chloride conducted by our parent company Degussa AG, headquartered in Frankfurt, Germany.

Detailed information is not available to date, as the report is presently subject to quality assurance by the quality assurance unit of the testing institute.

The following is a summary of the skin painting study.

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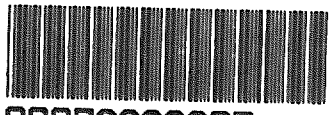
Test substance: Quab 188 - 65.79% 3-chloro-2-hydroxypropyltrimethylammonium chloride, 32.36% water

Study Design and Results
Carcinogenicity after repeated dermal application to mice (skin painting)

Dosage/route/duration:
Groups of 50 NMRI-mice of each sex were treated twice weekly with 0.2 ml of 0, 0.018, and 0.18 ml of 3-chloro-2-hydroxypropyltrimethylammonium chloride dissolved in a 10% aqueous ethanol solution. This corresponds to doses of 0, 13.8, and 138 mg/animal applied to the clipped dorsal skin (2 cm^2) of the animals. The study was terminated after 89 weeks for female animals and 105 weeks for male animals when the 25% survival limit was reached.



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Results

Microscopic examination of the application site showed a minimal increase in hyperceratosis and acanthosis probably reflecting a minimal irritation potential of the test substance after repeated application.

No tumors were observed at the site of application.

A statistically significant increased incidence of the number of animals with bronchio/alveolar tumors (56/100) and/or bronchio-alveolar hyperplasia (22/100) was observed in the high dose group compared to the control group (tumors: 27/100, hyperplasia: 7/100). In the low dose group the numerical incidence of those changes was also increased (tumors: 44/100, hyperplasia: 16/100), but the difference from the controls was not statistically significant.

A higher incidence of focal glandular hyperplasia of the stomach was observed in the high dose females only. This finding was mostly due to an increased incidence of minimal to slight hyperplasia. No other treatment related changes were observed in the study.

In conclusion, 3-chloro-2-hydroxypropyltrimethylammonium chloride caused minimal hyperkeratosis and acanthosis, but no local tumors at the site of application. However, an increased incidence of tumors and hyperplasia in the lungs of the animals seems to be a treatment related effect. The interpretation of these findings is difficult because the duration of the current study was considerably longer than the average study duration in published historic data of the same mouse strain. Additionally, even if the slightly increased tumor incidence represents a real effect, its biological significance is unclear and may represent a promoting effect rather than a tumor inducing phenomenon.

The slight increased incidence of glandular hyperplasia of the stomach seen in the high dose group may be due to unintended oral uptake of the test substance.

This product is sold as an aqueous solution which is only used for industrial applications.

Should you have any questions on the above, please contact me at (201) 807-3161.

Sincerely,

Jayne A. Pritchard
Regulatory Compliance Attorney